Attorney Docket No.: 5618.520-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Svendsen et al. Confirmation No: 2614

Serial No.: 10/734,510 Group Art Unit: 1652

Filed: December 12, 2003 Examiner: T. Saidha

For: Phytase Variants

APPEAL BRIEF UNDER 37 C.F.R. 41.37

Board of Patent Appeals and Interferences
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby appeal from the final rejection of claim 121 of the present application.

I. REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Novozymes A/S.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences relating to the instant application.

III. STATUS OF THE CLAIMS

Claims 105-135 remain pending in the application. Claims 1-104 have been canceled. Claims 105-120 and 122-135 have been allowed. A listing of all pending claims is included in the Claims Appendix. Claim 121, the only rejected claim, is included in this appeal.

IV. STATUS OF AMENDMENTS

The reply filed under 37 C.F.R. § 1.116 on June 19, 2006 was considered, but was stated as not overcoming the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 121 depends from allowed claim 105, which is directed to methods of producing a modified phytase, comprising introducing a mutation in an amino acid sequence of a phytase, wherein the modified phytase has phytase activity and the mutation is at one or more positions selected from the group consisting of 71; 72; 73; 74; 75; 76; 77; 78; 81; 82; 84; 116; 117; 119; and 120. The parent phytase from which the modified phytase is derived, is any phytase including but not limited to the *Peniophora lycii* phytase of SEQ ID NO: 7. The positions recited in claim 105 correspond to the positions of the amino acid sequence of the mature *P. lycii* phytase (SEQ ID NO: 7).

As described at page 5, lines 16-18 of the specification, a modified phytase or phytase variant is "a polypeptide or enzyme or a fragment thereof which exhibits phytase activity and which is amended as compared to a model phytase." Furthermore, as provided at page 5, lines 19-20, the model phytase is altered "by way of one or more amino acid or peptide substitutions, deletions, insertions and/or additions." Thus, a modified phytase has a different amino acid sequence relative to the parent phytase from which it is derived. For example, the different amino acid sequence may be obtained by substitution of an amino acid with a different amino acid.

The subject matter of claim 121 is directed to specific substitutions introduced in an amino acid sequence, namely 75W,F; 78D,S; 81A,G,Q,E; 82T; 84I,Y,Q,V; 116S; 119E; and 120L.

The positions recited in claim 105 are described at, *inter alia*, page 31, lines 22-35 of the specification. The substitutions recited in claim 121 are described at, *inter alia*, page 12, lines 1-22 of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are:

1. Whether claim 121 is anticipated under 35 U.S.C. 102(e) by Lassen et al. (U.S. Patent No. 6,060,298).

2. Whether claim 121 is patentable under the judicially created doctrine of obviousness-type double patenting over claims 1-3 of Lassen et al. (U.S. Patent No. 6,060,298).

VII. ARGUMENT

A. Claim 121 Is Not Anticipated Under 35 U.S.C. 102(e) by Lassen et al. (U.S. Patent No. 6,060,298)

Claim 121 is rejected under 35 U.S.C. 102(e) as being anticipated by Lassen et al. (U.S. Patent No. 6,060,298). Specifically, in the Advisory Action mailed July 11, 2006, the Office stated:

> Claim 121 is rejected under 35 U.S.C. 102(e) as being anticipated by Lassen et al. [U.S.P. 6,060,298]. Lassen et al. teach *Peniophora* phytase sequence (SEQ ID NO: 2) which is 100% [identical] to Applicants' SEQ ID NO: 7.
>
> In claim 121, there are modified positions which read upon the native *Peniophora* phytase sequence disclosed by Lassen et al. because the modification/substitution is with the same amino acid present in the native sequence, amounting to no modification at all. The mutational positions are 75W (Trp), 78S (Ser) and 84Q (Glu) corresponding to SEQ ID NO: 7. No difference is seen between the claimed method of modified sequence and that of a method of making the wild-type, as shown in the prior art of Lassen et al. The reference anticipates the claim.

Applicants respectfully submit that the Office's novelty rejection ignores limitations recited in claim 121, which are not described in Lassen et al. and therefore the 102 rejection is improper.

Lassen et al. disclose polypeptides exhibiting phytase activity, DNA sequences encoding the polypeptides, methods for producing the polypeptides, and processes of using the polypeptides. The Office is correct that a preferred embodiment of Lassen et al. is the *Peniophora lycii* phytase, which is the polypeptide of SEQ ID NO: 7 of the present application. The Office is also correct that the amino acid sequence of the wild-type *Peniophora lycii* phytase contains tryptophan at position 75, serine at position 78, and glutamine at position 84.

However, Lassen et al. do not disclose methods of producing a modified phytase by introducing a substitution selected from the group consisting of 75W,F; 78D,S; 81A,G,Q,E; 82T, as set forth in claim 121 of the present application.

As discussed above, a modified phytase is a phytase which has an altered amino acid sequence relative to a parent phytase by the introduction of an insertion, deletion or substitution. A substitution is a change of an amino acid with a different amino acid. Thus, the invention claimed in claim 121 does not read on a method of producing a wild-type polypeptide.

For the foregoing reasons, Applicants submit that claim 121 is novel over Lassen et al. and respectfully request reversal of this rejection.

B. Claim 121 Is Patentable Under The Doctrine Of Obviousness-Type Double Patenting Over Claims 1-3 of Lassen et al. (U.S. Patent No. 6,060,298)

Claim 121 is rejected under the doctrine of obviousness-type double patenting over claims 1-3 of Lassen et al. (U.S. Patent No. 6,060,298). Specifically, in the Advisory Action mailed July 11, 2006, the Office stated:

> Claim 121 is rejected under the judicially created doctrine of double patenting over claims 1-3 of U.S. Patent No. 6,060,298 [Lassen et al.] since the claims, if allowed, would improperly extend the 'right to exclude' already granted in the patent.
>
> The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claim 121 is anticipated by claims 1-3 of U.S. Patent No. 6,060,298, as explained above in the 102 rejection.

As provided above, the Office's novelty rejection, which is the basis for the double patenting rejection, is improper. Specifically, Lassen et al. do not disclose or suggest methods of producing a modified phytase by introducing a substitution selected from the group consisting of 75W,F; 78D,S; 81A,G,Q,E; 82T, as set forth in claim 121 of the present application.

Moreover, claims 1-3 of U.S. Patent No. 6,060,298 read as follows:

> 1. An isolated polypeptide exhibiting phytase activity and comprising the amino acid sequence of SEQ ID NO:2 or an amino acid sequence which is at least 90% homologous to this sequence, when homology is determined by GAP (version 8), using a GAP creation penalty of 5.0 and a GAP extension penalty of 0.3.
>
> 2. An isolated polypeptide exhibiting phytase activity and comprising the amino acid sequence of amino acid no. 31 to 439 of SEQ ID NO:2 or an amino acid sequence which is at least 90% homologous to this sequence, when homology is determined by GAP (version 8), using a GAP creation penalty of 5.0 and a GAP extension penalty of 0.3.
>
> 3. An isolated polypeptide exhibiting phytase activity, wherein said polypeptide is selected from the group consisting of:
>
> (a) a polypeptide encoded by a phytase-encoding part of
>
> (i) SEQ ID NO:1, or
>
> (ii) the DNA sequence cloned into plasmid PYES 2.0 present in *Eschericia coli* DSM 11312, and
>
> (b) a polypeptide which is at least 90% homologous to the polypeptide of (a) and which exhibits phytase activity, when homology is determined by GAP (version 8), using a GAP creation penalty of 5.0 and a GAP extension penalty of 0.3.

Claims 1-3 of U.S. Patent No. 6,060,298 are not directed to methods of producing polypeptides. During the prosecution of U.S. application no. 08/989,358, which issued as U.S. Patent No. 6,060,298, the Office issued an Office Action dated September 30, 1998 in which the following restriction requirement was made:

> Restriction to one of the following inventions is required under 35 U.S.C. 121:
>
> I. Claims 1-3 and 8-15, drawn to phytase protein and methods of using phytase, classified in class 435, subclass 196.
> II. Claims 4-7, drawn to DNA encoding phytase, transformed host cells and a method of making phytase, classified in class 435, subclass 69.1.

Since the Office made a restriction requirement between the claims directed to polypeptides and the claims directed to methods of making polypeptides because the claims were patentably distinct, Applicants submit that it is improper for the Office to use U.S. Patent No. 6,060,298 as a reference against the method claims of the instant application.

For the foregoing reasons, Applicants submit that claim 121 is patentable under the doctrine of obviousness-type double patenting. Applicants respectfully request reversal of this rejection.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the appeal is provided in the Claims Appendix attached hereto.

IX. EVIDENCE APPENDIX

Applicants are not relying on any evidence submitted pursuant to 37. C.F.R. 1.130, 1.131, and 1.132 of this title or of any other evidence entered by the examiner and relied upon by the appellant in the appeal.

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals and interferences pursuant to 37 C.F.R. 41.37(c)(1)(ii).

XI. CONCLUSION

For the foregoing reasons, Applicants submit that claim 121 is patentable under 35 U.S.C. 102 and the doctrine of obviousness-type double patenting. Accordingly, the final rejection of the claims should be reversed.

Respectfully submitted,

Date: January 17, 2007

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CLAIMS APPENDIX

Copy of Claims Involved in the Appeal

Claim 105 (Previously presented). A method of producing a modified phytase, comprising introducing a mutation in an amino acid sequence of a phytase, wherein the modified phytase has phytase activity and the mutation is at one or more positions selected from the group consisting of: 71; 72; 73; 74; 75; 76; 77; 78; 81; 82; 84; 116; 117; 119; and 120;
wherein each position corresponds to the position of the amino acid sequence of the mature *P. lycii* phytase (SEQ ID NO: 7).

Claim 106 (Previously presented). The method of claim 105, comprising introducing a mutation at position 71.

Claim 107 (Previously presented). The method of claim 105, comprising introducing a mutation at position 72.

Claim 108 (Previously presented). The method of claim 105, comprising introducing a mutation at position 73.

Claim 109 (Previously presented). The method of claim 105, comprising introducing a mutation at position 74.

Claim 110 (Previously presented). The method of claim 105, comprising introducing a mutation at position 75.

Claim 111 (Previously presented). The method of claim 105, comprising introducing a mutation at position 76.

Claim 112 (Previously presented). The method of claim 105, comprising introducing a mutation at position 77.

Claim 113 (Previously presented). The method of claim 105, comprising introducing a mutation at position 78.

Claim 114 (Previously presented). The method of claim 105, comprising introducing a mutation at position 81.

Claim 115 (Previously presented). The method of claim 105, comprising introducing a mutation at position 82.

Claim 116 (Previously presented). The method of claim 105, comprising introducing a mutation at position 84.

Claim 117 (Previously presented). The method of claim 105, comprising introducing a mutation at position 116.

Claim 118 (Previously presented). The method of claim 105, comprising introducing a mutation at position 117.

Claim 119 (Previously presented). The method of claim 105, comprising introducing a mutation at position 119.

Claim 120 (Previously presented). The method of claim 105, comprising introducing a mutation at position 120.

Claim 121 (Previously presented). The method of claim 105, wherein the mutation comprises a substitution selected from the group consisting of:
75W,F; 78D,S; 81A,G,Q,E; 82T; 84I,Y,Q,V; 116S; 119E; and 120L.

Claim 122 (Previously presented). The method of claim 105, wherein the phytase is an ascomycete phytase.

Claim 123 (Previously presented). The method of claim 122, wherein the phytase is an *Aspergillus* phytase.

Claim 124 (Previously presented). The method of claim 123, wherein the phytase is an *Aspergillus ficuum*, *Aspergillus fumigatus*, *Aspergillus nidulans*, *Aspergillus niger*, or *Aspergillus terreus* phytase.

Claim 125 (Previously presented). The modified phytase of claim 123, wherein the phytase is an *Aspergillus terreus*, CBS 116.46 phytase.

Claim 126 (Previously presented). The method of claim 105, wherein the phytase is a *Myceliophthora thermophila*, *Talaromyces thermophilus*, or *Thermomyces lanuginosus* phytase.

Claim 127 (Previously presented). The method of claim 126, wherein the phytase is a *Myceliophthora thermophila*, ATCC 34625 or ATCC 74340 phytase.

Claim 128 (Previously presented). The method of claim 126, wherein the phytase is a *Talaromyces thermophilus*, ATCC 20186 or ATCC 74338 phytase.

Claim 129 (Previously presented). The method of claim 126, wherein the phytase is a *Thermomyces lanuginosus*, NRRL B-21527 phytase.

Claim 130 (Previously presented). The method of claim 105, wherein the phytase is an ascomycete consensus phytase sequence.

Claim 131 (Previously presented). The method of claim 105, wherein the phytase is a basidiomycete phytase.

Claim 132 (Previously presented). The method of claim 131, wherein the phytase is an *Agrocybe pediades*, *Paxillus involutus*, *Peniophora lycii*, or *Trametes pubescens* phytase.

Claim 133 (Previously presented). The method of claim 132, wherein the phytase is a *Paxillus involutus*, CBS 100231 phytase.

Claim 134 (Previously presented). The method of claim 132, wherein the phytase is a *Paxillus involutus*, CBS 100231 Phy-A2 phytase.

Claim 135 (Previously presented). The method of claim 132, wherein the phytase is a *Trametes pubescens*, CBS 100232 phytase.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None